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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,716	12/14/2001	Jeanette McCarthy	MMI-005	5305
959	7590	10/03/2003	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			SHEINBERG, MONIKA B	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

10/017,716

## Applicant(s)

MCCARTHY, JEANETTE

## Examiner

Monika B Sheinberg

## Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-123 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☒ Other: *Detailed Action*.

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**DETAILED ACTION**

**Election/Restrictions**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 11-16, drawn to a method for selecting a particular clinical course of therapy to treat a vascular disease or disorder, classified in class 435, subclass 6.
- II. Claims 7-10, drawn to a method for identifying a subject who is a candidate for further diagnostic evaluation for a vascular disease or disorder, classified in class 435, subclass 6.
- III. Claim 17, 20 and 21, drawn to a method for determining whether a subject will benefit from implantation of a surgical procedure, classified in class 424, subclass 423.
- IV. Claims 18, 19, 22 and 23, drawn to a method for determining whether a subject will benefit from use of a vascular imaging procedure, classified in class 382, subclass 128.
- V. Claims 24 and 25, drawn to a computer readable medium, classified in class 707, subclass 100.
- VI. Claims 26-37 and 43-50, drawn to a method for diagnosing a vascular disease or disorder, classified in class 435, subclass 6.
- VII. Claims 38-40, drawn to a method for selecting the appropriate drug to administer to a subject, classified in class 424, subclass 9.2.
- VIII. Claims 41 and 42, drawn to a method for treating a subject having a disease or condition associated with a specific allelic variant, classified in class 435, subclass 6.
- IX. Claim 51-54, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1.
- XI. Claims 55-65, drawn to a method for determining the identity of one or more allelic variants of a polymorphic region of a 1L1RN gene, classified in class 435, subclass 6.
- XII. Claims 66-91, drawn to an internet-based method for assessing a subject's risk for vascular disease, classified in class 128, subclass 925.

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XIII. Claims 92 and 93, drawn to a communications method for generating a report, classified in class 370, subclass 259.

XIV. Claims 94-123, drawn to a method for generating a personal health assessment report for an individual, classified in class 703, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group IX and Groups I-IV, VI-VIII and X-XIII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acid of Group IX can be used for antisense therapy, which is not required for any of the claimed methods.

The inventions of Group V and Groups I-IV, VI-VIII and X-XIII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the computer readable medium of Group V can be used for storing alternate purposes such as numerical data storage.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products/apparatus, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups V and IX, are directed to products that are structurally and functionally different, and are not required one for the other. For example the computer readable medium of Group V stores instruction, while the nucleic acid of Group X has a multitude of uses as antisense therapy or drug screening. Therefore, a search and examination of all the products in one patent application would result in an undue burden, since the searches for the products are not co-extensive, the classification is different, and the subject matter is divergent.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods/processes, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-IV, VI-VIII and X-XIII are directed to methods that are functionally different and contain different method steps. Further the different method steps of each method are unobvious over one another and not required for the other patentably distinct methods. For example, the step of identifying a subject for a particular course of therapy is not required for a method for identifying a subject who is a candidate for further diagnostic evaluation. The following are examples that are requirements limited to the indicated group:

- I. selection of a clinical course of therapy (mechanical device versus surgical)
- II. selection of diagnostic evaluation tools (vascular imaging versus lifestyle analysis)
- III. determination of benefits of implantation of a surgical procedures
- IV. determination of benefits vascular imaging procedures
- VI. determination of phenotype, performance of vascular imagining, and allele combination likelihoods
- VII. selection of appropriate drug administration
- VIII. treatment
- X. identification of allelic variants
- XI. internet driven medical advice and assessment of vascular health
- XII. preparation for health assessment report requiring counseling, requests and authorizations
- XIII. generation of a health assessment report through the use of databases and an algorithm or a rule-based system

In addition, a search and examination of all the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

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**Conclusion**

A telephone call was made to Jim Cockfield on September 26, 2003 with respect to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souaya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 30, 2003  
Monika B. Sheinberg  
Art Unit 1634

*MB*

JEHANNE SOUAYA  
PATENT EXAMINER  
*Jehanne Souaya*  
9/30/03